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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/095,536	06/10/1998	JOHN A. KINK	OPHD-03282	9749

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MEDLEN & CARROLL, LLP  
101 HOWARD STREET  
SUITE 350  
SAN FRANCISCO, CA 94105

EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/29/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/095,536

Applicant(s)

KINK, JOHN A.

Examiner

Joseph F Murphy

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-12, 15-18 and 34-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-12, 15-18, 34-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Formal Matters***

Claims 34-48 were added in Paper No. 28, 4/28/2003. Claims 7-12, 15-18, 34-48 are pending and under consideration.

### ***Response to Amendment and Arguments***

Applicant's arguments and amendment filed in Paper No. 28, 4/28/2003 have been fully considered but they are not persuasive, for the reasons set forth below.

The rejection of claims 7-12, 15-18 under 35 U.S.C. 103(a) as being unpatentable over U.S. patent No. 5,723,120 (Brakenhoff et al.) in view of U.S. Patent No. 5,888,511 (Skurkovich et al.) and further in view of U.S. Patent No. 5,585,098 (Coleman et al.) has been withdrawn.

New issues are set forth below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-12, 15-18, 34-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent No. 5,723,120 (Brakenhoff et al.) in view of Doherty et al. (1992) and further in view of U.S. Patent No. 5,420,253 (Emery et al.).

The '120 patent discloses a method for treating IL-6 related diseases, said method comprising administering to a patient in need of such treatment a pharmaceutical composition containing an agent which can neutralize IL-6 activity, and discloses an IL-6 receptor antagonist effective for treating sepsis and a pharmaceutically acceptable carrier (column 3, lines 14-20). The '120 patent also discloses that it is known in the art that IL-6 activity can also be neutralized with antibodies directed to the IL-6 molecule (column 2, lines 29-40). Thus, the '120 patent discloses that sepsis, which is an IL-6 related disease, can be treated by neutralization of IL-6. It is thus a design choice of one of skill in the art to use either an IL-6 receptor antagonist, or antibodies to IL-6. In addition, the '120 patent further discloses that other agents may be combined with the IL-6 neutralizing agents include monoclonal antibodies directed to cytokines involved in the sepsis pathway, such as antibodies directed to IL-6, and antibodies directed to TNF (column 12, lines 44-50). The '120 patent thus teaches that sepsis may be treated by IL-6 activity neutralizing agents, including antibodies to IL-6, and that the treatment of sepsis can be by administration of compositions comprising anti-IL-6 and anti-TNF antibodies.

The '120 patent does not disclose methods of treatment by administration of a composition comprising antibodies to TNF-alpha, IL-6 and IFN-gamma. Doherty et al. teach that both TNF-alpha and IFN-gamma are important mediators of septic shock (page 1666,

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column 2). Doherty et al. also teach that mice treated with either anti-IFN-gamma polyclonal antibodies or anti-TNF polyclonal antibodies had a dose dependent improvement in survival after a lethal dose of LPS (page 1669, columns 1 and 2 and Figure 3 page 1667), an animal model of sepsis. Doherty et al. further teach that there is an essential cytokine interaction during sepsis in which IFN-gamma activity is required for the lethal effects of TNF (page 1670c column 1).

Neither the '120 patent nor Doherty teach antibodies derived from chicken. The '253 patent discloses a method for purifying high yields of IgG (IgY) immunoglobulin from chicken egg yolk (see Abstract). The '253 patent discloses that antibodies derived from egg yolk provide significant advantage over their mammalian counterparts because they provide a higher level of specificity and reduced amount of undesirable side effects. Egg yolks contain high levels of IgG (IgY) immunoglobulin (column 1, lines 11-21), it is also less labor intensive to collect immunoglobulin-containing eggs from birds than to separate it from the animal serum. The '253 patent suggests that anti-TNF antibodies could be produced by this method (column 4, lines 43-44) and that these antibodies could be administered orally, parenterally or by injection when used to immunize animals or humans (column 8, lines 49-68).

Therefore, it would have been obvious to one of skill in the art at the time the invention was made to practice a method of treating patients with sepsis with therapeutic compositions comprising anti-TNF, anti-IL-6 and anti-IFN-gamma antibodies that are avian in source. The motivation to combine anti-IL-6 and anti-TNF antibodies is provided in the '120 patent which discloses that sepsis may be treated by IL-6 activity neutralizing agents, including antibodies to IL-6, and that the treatment of sepsis can be by administration of compositions comprising anti-IL-6 and anti-TNF antibodies, and in Doherty et al, which teaches that the lethal effects of TNF

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are dependent on IFN-gamma activity which can be blocked by anti-IFN-gamma antibodies.

The motivation to use antibodies derived from avian sources is provided in the '253 patent which discloses the advantages of egg yolk antibodies (column 1, lines 11-21).

***Conclusion***

No claim is allowed.


***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.


The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
September 24, 2003



YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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